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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,331	09/16/2003	Laurent Humeau	397272000401	4194

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,331	HUMEAU ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction Requirement

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communications filed 27 September, 2004, and 01 June, 2005. Claims 1-82 are pending in the instant application. Applicants are hereby advised that the office action mailed 30 June, 2004, has been vacated in favor of the following action.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 1-30, 33-64, and 66-71, drawn to *in vitro/ex vivo* methods of transducing primary cells of the hematopoietic system using a lentiviral vector and cell surface binding molecule, classified in class 435, subclass 456.

b. Group II, claim(s) 31 and 32, drawn to a method for the introduction of transduced cells into a living subject, classified in class 435, subclass 325.

c. Group III, claim(s) 65, drawn to a method of introducing a transduced cell into a tissue, organ, blastocyst, or embryonic stem cell, classified in class 435, subclass 325.

d. Group IV, claim(s) 72 and 73, drawn to a method for the stable transduction of hematopoietic stem cells isolated from an HIV-infected individual, classified in class 435, subclass 456.

e. Group V, claim(s) 74-77 and 80-82, drawn to a composition formulated for the treatment of a viral infection comprising a transduced cell, classified in class 435, subclass 325.

f. Group VI, claim(s) 74, 75, 78-80, and 82, drawn to a composition formulated for the treatment of a tumor comprising a transduced cell, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant situation each of the identified groups is directed toward a different method that accomplishes different scientific objectives and employs disparate methodology steps and scientific reagents. For instance, Group I is simply directed toward a method of stably transducing hematopoietic stem cells by administering a vector and compound. However, Group II involves the administration of a transduced cell into a patient. Clearly these methodologies achieve different scientific objectives and employ different reagents/protocols.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the compositions has a different formulation designed to achieve a specific purpose (i.e., treatment of viral infection or cancer). The molecules required to target a composition to a virally infected cell differ considerably from those required to target a composition toward a tumor cell. Clearly, these are independent and distinct inventions based upon the formulation differences.

Inventions I-IV and V/VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant scenario, none of the methodologies of Groups I-IV employ the pharmaceutical compositions of Groups V and

VI. Accordingly, each invention is clearly directed toward a different inventive concept.

Applicants are further advised that if Group I, II, or III is elected, the following restriction requirement also applies: 1) applicants are required to elect and identify the precise structural/functional characteristics of the lentiviral vector employed (i.e., specify viral origin [HIV-1, HIV-2, SIV, EIAV, etc.], genomic structure [nef-deficient, tat-deficient, rev-deficient, pseudotyped with VSV G envelope, etc.]); 2) applicants are required to elect and identify a specific cell surface binding molecule (i.e., an FLT-3 ligand, a TPO ligand, a Kit ligand, etc.); and 3) applicants are required to elect a single target cell (i.e., $CD4^+$, $CD8^+$, $CD34^+$, etc.). Each lentiviral vector or pseudo vector employed is structurally and functionally different and will require separate searches. Each cell surface binding molecule is also structurally and functionally distinct and will necessitate independent searches for each molecule. Finally, each of the identified target cell populations has unique genotypic/phenotypic characteristics that necessitate different transduction strategies and requires searches that are not coextensive in nature. Accordingly, each combination of lentiviral vector, cell surface binding molecule, and cell target constitutes an independent and distinct invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

37 C.F.R. § 1.48(b)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (571) 273-8300. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access

to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

11 July, 2005